IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants

: Coates et al.

Serial No.

: 07/835964

Filed

: February 20, 1992

For

: 1,3-OXATHIOLANE NUCLEOSIDE ANALOGUES

New York, New York September 17, 1992

Hon. Commissioner of Patents and Trademarks Washington, D.C. 20231

STATEMENT UNDER 37 C.F.R. § 1.56 AND § 1.97

Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97, applicants, through their attorney, make of record the following documents* in the above-identified application:

United States Patent Publications

4,336,381

5,039,667

**5,047,407

European Patent Publications

EP 0 212 409 B1

EP 0 302 760

EP 0 337 713 A2

EP 0 349 242 A2

EP 0 363 582 A1

**EP 0 382 526 A2

^{*} Copies are enclosed. For the convenience of the Patent Examiner, applicants have enclosed a completed Form PTO-1449 listing these documents.

^{**} Applicants believe these documents may be relatively more pertinent than others of the documents cited herein.

Great Britain Patent Publications

GB 2 063 257 A

GB 2 230 266 A

International Patent Publications

WO 89/04662

**WO 90/12023

WO 91/00282

**WO 91/01326

**WO 91/11186

<u>Articles</u>

**Baba et al., "Both 2',3'-Dideoxythymidine and its 2',3'-Unsaturated Derivative (2',3'-Dideoxythymidinene) are Potent and Selective Inhibitors of Human Immunodeficiency Virus Replication in vitro", Biochemical and Biophysical Research Communications, 142(1) pp. 128-134 (1987) ("Baba");

**Balzarini et al., "Potent and Selective Anti-HTLV-III/LAV Activity of 2',3'-Dideoxycytidinene, the 2',3'-Unsaturated Derivative of 2',3'-Dideoxycytidine",

Biochemical and Biophysical Research Communications, 140(2),
pp. 735-742 (1986) ("Balzarini");

**Belleau et al., "Design And Activity Of A Novel Class Of Nucleoside Analogs Effective Against HIV-1", Fifth International Conference on AIDS, Montreal, Canada, Abstract T.C.O. 1 (1989) ("Belleau");

Carlisle et al., "Cellular Pharmacology Of The Anti-HIV Agent BCH-189 (2'-Deoxy-3'-Thiacytidine) In Human Peripheral Blood Mononuclear Cells (PBMC)", American Association for Cancer Research Proceedings, 31, abstract 2435, (1990) ("Carlisle");

Gosselin et al., "Systematic Synthesis And Biological Evaluation Of α- and β-D-Lyxofuranosyl Nucleosides Of The Five naturally Occurring Nucleic Acid Bases", J. Med. Chem., 30, pp. 982-991 (1987) ("Gosselin");

Herdewijn et al., "3'-Substituted 2',3'-Dideoxynucleoside Analogues as Potential as Potential Anti-HIV (HTLV-III/LAV) Agents", <u>J. Med. Chem.</u>, 30, pp. 1270-1278 (1987) ("Herdewijn");

Lin et al., "Synthesis and Antiviral Activity of Various 3'-Azido, 3'-Amino, 2',3'-Unsaturated, and 2',3'-

Dideoxy Analogues of Pyrimidine Deoxyribonucleosides against Retroviruses", J. Med. Chem., 30, pp. 440-444 (1987) ("<u>Lin</u>");

**Mitsuya et al., "3'-Azido-3'-Deoxythymidine (BW A509U): An Antiviral Agent that Inhibits the Infectivity and Cytopathic Effect of Human T-Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus in vitro", Proc. Natl. Acad. Sci. USA, 82, pp. 7096-7100 (1986) ("Mitsuya-1");

Mitsuya et al., "Inhibition of the <u>in vitro</u> Infectivity and Cytopathic Effect of Human T-Lymphotrophic Virus Type III/Lymphadenopathy-Associated Virus (HTLV-III/LAV) by 2',3'-Dideoxynucleosides", Proc. Natl. Acad. Sci. USA, 83, pp. 1911-1915 (1986) ("Mitsuya -2"); ("<u>Mitsuya -2</u>");

**Wainberg et al., "Anti-HIV Activity, Toxicity And Pharmacokinetics Of Totally Novel Nucleoside Analogs, " Fifth International Conference on AIDS, Montreal, Canada, Abstract M.C.P. 63, p. 552, (1989) ("Wainberg-1").

**Wainberg et al., "Characterization Of AZT-Resistant Isolates Of HIV-1: Susceptibility To Deoxythiacytidine And Other Nucleosides", Sixth International Conference on AIDS, San Francisco, California, Volume 3, Abstract S.B.87, p. 117 (1990) ("Wainberg-2");

None of the above-cited documents, made of record by applicants herein, renders unpatentable, either alone or in any combination thereof, the amended claims of this application. Applicant requests that these documents: (1) be fully considered by the Examiner during examination of this application, (2) be listed on any Notice of References Cited issued in this application, and (3) be printed on any patent that may issue from this application.

I Hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on

of Person Signing

Signaturé of Person Signing

Respectfully submitted,

James F. Haley, Jr. (Reg. No. 27,794) Leslie A. McDonell (Reg No. 34,872)

Attorneys for Applicants

C/O FISH & NEAVE

875 Third Avenue

New York, New York 10022

(212) 715-0600





Applicant(s) : COATES ET AL.

Title : 1,3-OXATHIOLANE NUCLEOSIDE ANALOGUES

Filed Date : FEBRUARY 20, 1992

Serial No. : 07/835,964

"EXPRESS MAIL" mailing label number EF477297931US Date of Deposit MARCH 15, 1994

I hereby certify that this paper/fee is being deposited with the United States Postal Service "EXPRESS MAIL POST OFFICE TO ADDRESSEE" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to the Hon. Commissioner of Patents and Trademarks, Washington, D.C. 20231.

ANTONIO MELENDEZ

PETITION FOR EXTENSION OF TIME & CHECK \$840.00 & RESPONSE & AMENDMENT FILED

Modified PTO 1082

Or Other Than A Small Entity

•

Attorney Docket No. <u>IAF-14</u>

Examiner

John M. Ford

croup Art Unit :

1202

Applicant(s)

Coates et al.

Serial No.

07/835,964

Filed

February 20, 1992

For

1,3-OXATHIOLANE NUCLEOSIDE ANALOGUES

Hon. Commissioner of Patents

:

:

New York, New York

and Trademarks

March 15, 1994

Washington, D.C. 20231

TRANSMITTAL LETTER

Sir:

Transmitted herewith: [] a Preliminary Amendment; [X] a Response to Examiner's Action; [] a Supplemental Amendment; [] a substitute Specification; [X] a Declaration Under 37 C.F.R. § 1.132; [] a Supplemental Declaration; [] a Power of Attorney; [] an Associate Power of Attorney; [] formal drawings; to be filed in the above-identified patent application.

FEE FOR ADDITIONAL CLAIMS

- [X] A fee for additional claims is not required.
- [] A fee for additional claims is required. The additional fee has been calculated as shown below:

| | CLAIMS REMAINI AFTER AMENDME | | | | ? | PRESENT EXTRA | | RATE | 2 | ADDITIONAL FEES |
|--|---|---|---|----|---|------------------|-------|------|---|--------------------|
| TOTAL C | CLAIMS | _ | | * | | | x | \$22 | = | \$ |
| INDEPEN | IDENT | _ | · | ** | = | | x | \$74 | = | \$ |
| | FIRST PRESENTATION OF A MULTIPLE DEPENDENT CLAIM | | | | | | | | = | \$ |
| * If less than 20, insert 20. ** If less than 3, insert 3. | | | | | | | TOTAL | | | \$ |

- A check in the amount of \$_____ in payment of the fee for additional claims is transmitted herewith.
- [X] The Commissioner is hereby authorized to charge payment of any additional fees required under 37 C.F.R. § 1.16 in connection with the paper(s) transmitted herewith, or credit any overpayment of same, to Deposit Account No. 06-1075. A duplicate copy of this transmittal letter is transmitted herewith.
- [] Please charge \$_____ to Deposit Account No. 06-10 payment of the filing fee. A duplicate copy of this _____ to Deposit Account No. 06-1075 in transmittal letter is transmitted herewith.

EXTENSION FEE

- [X]The following extension is applicable to the Response filed herewith; [] \$110.00 extension fee for response within first month pursuant to 37 C.F.R. § 1.17(a); [] \$360.00 extension fee for response within second month pursuant to 37 C.F.R. § 1.17(b); [X] \$840.00 extension fee for response within third month pursuant to 37 C.F.R. § 1.17(c); [] \$1,320.00 extension fee for response within fourth month pursuant to 37 C.F.R. § 1.17(d).
 - A check in the amount of [] \$110.00; [] \$360.00; [X] \$840.00; [] \$1,320.00; in payment of the extension fee is transmitted herewith.
 - The Commissioner is hereby authorized to charge payment of any additional fees required under 37 C.F.R. § 1.17 in connection with the paper(s) transmitted herewith, or to credit any overpayment of same, to Deposit Account No. 06-1075. A duplicate copy of this transmittal letter is transmitted herewith.
 - Please charge the [] \$110.00; [] \$ 360.00; [] \$840.00; [] \$1,320.00; extension fee to Deposit Account No. 06-1075. A duplicate copy of this transmittal letter is transmitted herewith.

James F. Haley, Jr. (Reg. No. 27,794 Leslie A. McDonell (Reg. No. 34,872)

Attorneys for Applicants

c/o FISH & NEAVE

1251 Avenue of the Americas New York, New York 10020 Tel.: (212) 596-9000